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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,319	08/19/2003	Michael D. Ruff	019031-000010	3826

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/643,319

Applicant(s)

RUFF ET AL.

Examiner

Simon J. Oh

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 43-53 and 55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-53 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

Art Unit: 1618

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment and response, both received on 17 January 2006.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norling *et al.* (U.S. Patent No. 5,958,458)

The Norling *et al.* patent teaches a pharmaceutical multiple unit formulation in the form of coated cores. The core material is selected from various materials that include calcium carbonate, calcium silicate, calcium magnesium silicate, calcium phosphate, and kaolin (See Abstract). Various substances may be applied as coatings to the cores, including waxes, hydrogenated oils, and glyceryl monostearate. The coating material may be admixed with excipients that include colloidal silicon dioxide, talc, and magnesium stearate. The coating material may further comprise plasticizers, such as castor oil, mineral oil, and coconut oil (See Column 9, Line 41 to Column 10, Line 57). Film coatings comprising polymers such as ethylcellulose may be included in the disclosed composition (See Column 9, Lines 43-50). The

Art Unit: 1618

disclosed composition may be embodied in various formulations, including powders, granules, tablets, as well as liquid formulations (See Column 13, Lines 29-36). The cores may also comprise an active substance, which may be coated onto the surface of the cores (See Column 11, Lines 57-67). The active substance may be selected from various broad categories of agents, including insulin (See Column 7, Lines 60-67). The patent discloses examples where inert cores are prepared and where varying amounts of various coating materials are applied to these cores (See Example 1A to Example 10).

It is the position of the examiner that the instantly claimed invention is made obvious by the disclosure of the prior art. With regard to the selection of the particular type of calcium phosphate used in Claim 55, it is the position of the examiner that as the prior art has broadly disclosed the use of calcium phosphate, that particular claim limitation does not lend patentability unto the instantly claimed invention without a showing of unexpected results by one of ordinary skill in the art. Furthermore, the prior art disclosure of the core material being coated with various excipients such as hydrogenated oils and magnesium stearate, it is the position of the examiner that this disclosure reads on what the applicant was chosen to define as a permeation enhancer. Thus, the instantly claimed invention is *prima facie* obvious.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

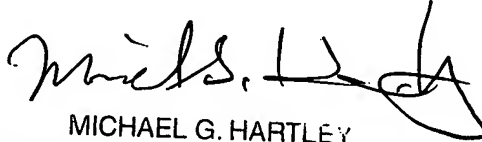
Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1618

sj0

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER